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EXAMINER

PATEL, NIHIR B

ART UNIT

PAPER NUMBER

3743

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Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims **1-14, 20-23 and 31-35** are rejected under 35 U.S.C. 102(b) as being anticipated by Wallace et al. (US 5,941,888).

3. As to **claim 1**, Wallace teaches a tissue connector assembly comprising two clips **102 and 104** each is sized and shaped to attach tissues and hold the tissue together therein, and a bridge portion **106** connecting the two clips and spacing the clips from one another (**see figure 1**).

4. As to **claim 2**, Wallace teaches an apparatus wherein the bridge portion is substantially straight (**see figure 1**).

5. As to **claim 3**, Wallace teaches an apparatus wherein the two clips have an open configuration and a closed configuration (**see column 5 lines 47-55**).

6. As to **claim 4**, Wallace teaches an apparatus wherein the bridge portion provides a predetermined spacing between the clips in the closed configuration (**see figure 1**).

7. As to **claim 5**, Wallace teaches an apparatus wherein at least one of the two clips is a self-closing clip (**see column 5 lines 47-55**).

8. As to **claim 6**, Wallace teaches an apparatus wherein the self-closing clip comprises shape memory material (**see column 5 lines 47-55**).

9. As to **claim 7**, Wallace teaches an apparatus that further comprises a coil surrounding a substantial length of the closing clip (**see figure 1**).

10. As to **claim 8**, Wallace teaches an apparatus wherein the closed configuration is an unbiased configuration (**see column 5 lines 47-55**).

11. As to **claim 9**, Wallace teaches an apparatus wherein the closed configuration is a loop (**see figure 5**).

12. As to **claim 10**, Wallace teaches an apparatus wherein the open configuration is a biased configuration, and wherein the release mechanism (**such as catheter**) having a first position to bias self-closing clip in the open configuration.

13. As to **claim 11**, Wallace teaches an apparatus wherein the closed configuration is an unbiased configuration, and wherein the release mechanism has a second position (**via a pusher as described in US 4,994,069**) to un-bias the self-closing clip into the closed configuration.

14. As to **claim 12**, Wallace teaches an apparatus that further comprises a coil surrounding a substantial length of the self-closing clip, where the coil is coupled at one point on the self-closing clip and releasably coupled via the release mechanism at a second point on the self-closing clip.

15. As to **claim 13**, Wallace teaches an apparatus wherein the first position provides for compressing the coil between the first point and second point to form the biased configuration.

16. As to **claim 14**, Wallace teaches an apparatus wherein the second position provides for releasably uncoupling the coil from the second point to form the unbiased configuration.

17. As to **claim 20**, Wallace teaches an tissue connector assembly comprising a surgical fastener comprising two clips **102 and 104** sized and shaped to attach tissues and hold the tissues

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therein including at least one self-closing clip having an open configuration and a closed configuration, where the open configuration is a biased configuration and the closed configuration is an unbiased configuration, and a bridge portion **106** having a substantially straight portion connecting the two clips; a release mechanism (**catheter**) having a first position to bias the self-closing clip in the open configuration, and a second position to un-bias the self-closing clip into the closed configuration (**see figures 1 and 5**).

18. As to **claim 21**, Wallace teaches an apparatus that further comprises a coil surrounding a substantial length of the self-closing clip, where the coil is coupled at one point on the self-closing clip and releasably coupled via the release mechanism at a second point on the self-closing clip.

19. As to **claim 22**, Wallace teaches an apparatus wherein the first position provides for compressing the coil between the first point and second point to form the biased configuration.

20. As to **claim 23**, Wallace teaches an apparatus wherein the second position provides for releasably uncoupling the coil from the second point to form the unbiased configuration.

21. As to **claim 31**, Wallace teaches a surgical clip apparatus comprising an elongated member, a pair of coils **102 and 104** surrounding at least a portion of the elongated member, the pair of coils being serially arranged and spaced from one another along the elongated member (**see figure 1**), the elongated member being shape memory material and having an unbiased shape, which includes a plurality of loops and a biased shape, the elongated member tending to move toward the unbiased shape from the biased shape (**see column 5 and figures 1 and 5**).

22. As to **claim 32**, Wallace teaches an apparatus wherein the loops are spaced from one another (**see figures 1 and 5**).

23. As to **claim 33**, Wallace teaches an apparatus wherein each coil surround at least a portion of a different one of the loops.

24. As to **claim 34**, Wallace teaches an apparatus wherein each coil has an outer end and an inner end, the inner ends being spaced from one another (**see figures 1 and 5**).

25. As to **claim 35**, Wallace teaches an apparatus wherein each coil has an outer end and an inner end, and the elongated member has two enlarged end portions, further including a resistant coupled to the elongated member adjacent to each of the inner ends (**see figure 1**).

26. As to **claim 39**, Wallace teaches an apparatus wherein each of the clips has a memory set loop configuration and a deformed configuration, and the bridge portion separates the loops from one another when the clips are in their memory set configuration (**see figures 1 and 5**).

27. As to **claim 40**, Wallace teaches an apparatus wherein each of the clip has a free end (**see figure 1**).

28. As to **claim 41**, Wallace teaches a tissue connector assembly that comprises an elongated member having a first loop shaped portion adapted to hold tissue therein, a second loop shaped portion adapted to hold tissue therein, and a bridge portion bridging the first and second loop shaped portions, each loop shaped portion having a free end and being deformable into a second deformed shape where it tends to return towards its loop shape (**see figures 1 and 5**).

29. As to **claim 42**, Wallace teaches an apparatus wherein the elongated member are not coils (**see figure 1**).

30. As to **claims 43 and 44**, Wallace teaches an apparatus wherein the elongated member is a wire (**see figure 1**) that comprises nitinol.

31. As to **claim 45**, Wallace teaches an apparatus that further comprises a pair of coils, one of the coils surrounding at least a portion of one of the first loop shaped portion and the other of the coils surrounding at least a portion of the second loop shaped portion (**see figure 1**).

32. As to **claim 46**, Wallace teaches an apparatus wherein each coil has an outer end and an inner end, and the elongated member has two enlarged end portions, further including a restraint coupled to the elongated member adjacent to each of the inner ends.

33. As to **claim 47**, Wallace teaches an apparatus wherein the bridge portion is substantially straight (**see figure 1**).

34. As to **claim 48**, Wallace teaches a tissue collector apparatus that comprises an elongated member having a first loop shaped portion, a second loop shaped portion and a bridge portion bridging the first and second loop shaped portions, each loop shaped portion having a piercing element at one end and a portion that merges into the bridge shaped portion, each loop shaped portion being deformable into a second deformed shape and having the property of tending to return towards its loop shape (**see figure 1**).

35. As to **claim 49**, Wallace teaches an apparatus wherein the elongated member are not coils (**see figure 1**).

36. As to **claims 50 and 51**, Wallace teaches an apparatus wherein the elongated member is a wire (**see figure 1**) that comprises nitinol.

37. As to **claim 52**, Wallace teaches an apparatus that further comprises a pair of coils, one of the coils surrounding at least a portion of one of the first loop shaped portion and the other of the coils surrounding at least a portion of the second loop shaped portion (**see figure 1**).

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38. As to **claim 53**, Wallace teaches an apparatus wherein each coil has an outer end and an inner end, and the elongated member has two enlarged end portions, further including a restraint coupled to the elongated member adjacent to each of the inner ends.

39. As to **claim 54**, Wallace teaches an apparatus wherein the bridge portion is substantially straight (see **figure 1**).

Claim Rejections - 35 USC § 103

40. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

41. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

43. Claims **15-19, 24-26, 36-38 and 55** are rejected under 35 U.S.C. 103(a) as being unpatentable over Chervitz et al. (US 5,645,568) in view of Wallace et al. (US 5,941,888).

44. As to **claims 15 and 55**, Chervitz discloses the applicant's invention as claimed with the exception of providing two self-closing clips that are attached to the two arms of the suture body. However, use of two self-closing clips in a surgical fastening device was known at the time the invention was made. Specifically, Wallace teaches a tissue connector assembly having a surgical

fastener having two clips **102 and 104** fully capable of attaching tissues and a bridge portion **106** connecting the two clips (**see figure 1**). Therefore it would have been obvious to modify the tissue connection device of Chervitz to have the addition of two self-closing clips, as taught by Wallace, on either end of the suture body arms for the purpose of enhanced attachment of tissues.

45. **As to claim 16**, Chervitz as modified discloses that as applied to claim 15. Further comprises a release mechanism, that activates the release of the two piercing members from the respective two ends would be obvious to one with ordinary skill in the art, for it has been held that to make something separable involves only routine skill in the art.

46. **As to claim 17**, Chervitz as modified discloses that as applied to claim 16. Further, a release mechanism that activates the closing of the self-closing clip would be obvious given the combination.

47. **As to claim 18**, Chervitz as modified discloses that as applied to claim 15, as well as, a suture, wherein the coupling of the first tissue-piercing member to the first end includes suture, and wherein the coupling of the second tissue piercing member to the second end includes a suture.

48. **As to claim 19**, Chervitz as modified disclose that as applied to claim 18, as well as suture of the first coupling and the suture of the second coupling are between about 10 mm and about 300 mm in length.

49. **As to claim 24**, Chervitz discloses the applicant's invention as claimed with the exception of providing two self-closing clips that are attached to the two arms of the suture body. However, use of two self-closing clips in a surgical fastening device was known at the time the invention was made. Specifically, Wallace teaches a tissue connector assembly having a surgical

fastener having two clips **102 and 104** fully capable of attaching tissues and a bridge portion **106** connecting the two clips (see **figure 1**). Therefore it would have been obvious to modify the tissue connection device of Chervitz to have the addition of two self-closing clips, as taught by Wallace, on either end of the suture body arms for the purpose of enhanced attachment of tissues.

50. **As to claim 25**, Chervitz as modified discloses that as applied to claim 15. Further comprises a release mechanism, that activates the release of the two piercing members from the respective two ends would be obvious to one with ordinary skill in the art, for it has been held that to make something separable involves only routine skill in the art.

51. **As to claim 26**, Chervitz as modified discloses that as applied to claim 25. Further, a release mechanism that activates the closing of the self-closing clip would be obvious given the modification.

52. **As to claim 31**, Chervitz discloses the applicant's invention as claimed with the exception of providing an elongated member, a pair of coils surrounding at least a portion of the elongated member where the pair of coils are serially arranged and spaced from one another along the elongated member, the elongated member being shape member material and having an unbiased shape that includes a plurality of loops and a biased shape. The elongated member tends to move toward the unbiased shape from the biased shape. However, use of a pair of coils in a surgical fastening device was known at the time the invention was made. Specifically, Wallace discloses a tissue connector assembly having a surgical fastener having a pair of coils **102 and 104** being serially arranged and spaced from one another along the elongated member, wherein the elongated member tends to move toward the unbiased shape from the biased shape. Therefore it would have been obvious to modify the tissue connection device of Chervitz to have

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the addition of a pair of coils, as taught by Wallace for the purpose of enhanced attachment of tissues.

53. **As to claim 37**, Chervitz as modified disclose that as applied to claim 36. Further, a first coupling releasably coupled in the first end portion of the surgical slip to the first needle would be obvious to one with ordinary skill in the art, for it has been held to make something separable involves only routine skill in the art.

54. **As to claim 38**, Chervitz as modified disclose that as applied to claim 37. Further, a second coupling couples the second end portion of the clip to a second needle would have been obvious to one with ordinary skill in the art, for it has been held to make something separable involves only routine skill in the art.

Response to Arguments

55. Applicant's arguments filed on June 18th, 2006 have been fully considered but they are not persuasive. The applicant argues that figure 1 is the examiner's hypothetical drawing and is not present in the Wallace patent and therefore should not form a basis for a rejection under 35 U.S.C. 102. The examiner disagrees. Figure 1 and 5 of Wallace reference does form the basis for a rejection under 35 U.S.C. 102. The applicant argues that the catheter in Wallace cannot simultaneously extend into two aneurysm openings. The examiner disagrees. Referring to column 11 lines 15 to 25, Wallace states "...Depending on the constraints such as the condition and size of the occlusion...", in a broad sense the examiner takes the position that the phrase "the condition and size of the occlusion" can be defined as two aneurysm. The process for removing the catheter from patient is described in column 11 lines 35-40).

56. Claims 1-26 and 31-38 are still rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 7, 9, 11-13, 15-17, 19, 21, 23, 25-30, 33, 35-43, 46 and 48-52 of US Patent 6,551,332 as stated in the previous office action dating December 8th, 2005.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

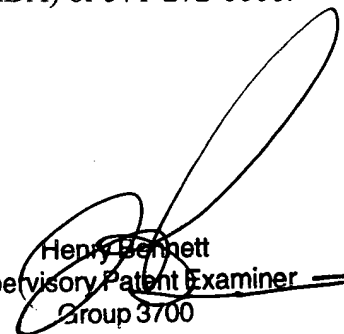
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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